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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,690	08/03/2006	David Strand	005092-00073	8430
22910 7590 05/13/2009 BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601			EXAMINER KWAK, DEAN P	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/537,690	STRAND ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DEAN KWAK	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 11, 17, 19, 34-36, 38-45, 47, 49, 50 and 54-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-16, 18, 20-33, 37, 46, 48, 51-53, 59-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 June 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>04/10/2008</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to because **Fig. 3 details are unclear**. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4-10, 12-13, 15-16, 18, 20-21, 31, 33, 37, 46, 48, 51-53, 60-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Bard (US 5,580,523).

Regarding Claim 1, Bard discloses a microfluidic substrate assembly comprising:

- a substrate body (e.g., assembly board, C6/L42 & Fig. 3 (40)) comprising:
- at least one fluid inlet port (Fig. 3 (81));
- at least one microscale fluid flow channel within the substrate in fluid communication with the inlet port (see channels Fig. 3 (81-84)); and
- a plurality of sockets (see Figs. 1d & 3), each socket configured to receive an operative component (C6/L35-40 & Fig. 3 (100, 60, 70)), wherein at least one socket is in communication with the microscale fluid flow channel (see Fig. 3).

Regarding Claims 4-10 & 12-13, Bard further discloses the microfluidic substrate assembly wherein:

- the substrate assembly is generally planar (see Fig. 3);
- the plurality of sockets are located in an upper surface of the generally planar body (see Fig. 3);
- the plurality of sockets are located in a grid array (see Fig. 3);
- at least one of the sockets is in fluid communication with the microscale fluid flow channel (see Fig. 3);

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- at least one of the sockets is in fluid communication with at least one other of the sockets (Figs. 3, 4 & C7/L5-9);
- multiple sockets of the sockets have the same configuration (see Fig. 3);
- at least one of the sockets is in electrical communication with at least one other of the sockets (see electrical signal communication in Fig. 4 & C7/L5-20);
- the substrate body further includes at least one fluid outlet port (Fig. 3 (84)) in fluid communication with the fluid inlet port (see Fig. 3); and
- a fluid reservoir (e.g., reaction chamber, C5/L22 & Fig. 1b (4)) in fluid communication with the microscale fluid flow channel.

Regarding Claims 15, 16, 18, 20 & 21, Bard further discloses the microfluidic substrate assembly wherein the substrate body further comprises:

- at least one data port (C4/L33-34); and at least one data channel within the substrate body in communication with the data port and at least one of the sockets (C4/L25-46 & Fig. 4);
- the data channel is in electrical communication with the data port (C4/L25-46);
- the data channel is in electrical communication with at least one of the sockets (C4/L25-46);
- the data channel is bi-directional (see Fig. 4 where data being communicating bi-directionally); and
- the substrate body further comprises a data output port in communication with the data channel (C4/L25-46).

Regarding Claim 31, Bard disclose a microfluidic substrate assembly comprising:

- a substrate body (e.g., assembly board, C6/L42 & Fig. 3 (40)) comprising:
- at least one fluid inlet port (Fig. 3 (81));
- at least one microscale fluid flow channel within the substrate body in fluid communication with at least one fluid inlet port (see channels Fig. 3 (81-84)) for transport of fluid to be tested;
- a plurality of sockets (see Figs. 1d & 3), each configured for receiving an operative component and in communication with at least another of the sockets (C6/L35-40 & Fig. 3 (100, 60, 70)), wherein at least one socket is in communication with the microscale fluid flow channel (see Fig. 3); and
- at least one operative component mounted in a corresponding one of the sockets (see Fig. 3).

Regarding Claims 33, 37, 46, 48 & 51, Bard further disclose the microfluidic substrate assembly wherein:

- the at least one of the sockets is in fluid communication with the microscale fluid flow channel (see Fig. 3);
- the substrate body further comprises at least one fluid outlet port (Fig. 3 (84)) in fluid communication with at least one fluid inlet port (see Fig. 3);

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- the at least one operative component comprises a device operative: as a component that is a spectroscopy detector, and/or as a chromatographic, electrophoretic (C4/L47-51);
- the at least one operative component is operative to directly contact a fluid in the microscale fluid flow channel (see Fig. 3); and
- the operative component is permanently mounted in a socket (e.g., pins connect the units, C6/L41 & Fig. 3 (30-33)).

Regarding limitations recited in Claim 52 which are directed to a manner of operating disclosed device (e.g. “using potting compound”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Regarding Claims 53, 60-61, Bard further disclose the microfluidic substrate assembly wherein:

- the operative component is removably mounted in a socket (e.g., detachable reaction units, C4/L54);

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- at least one data port (C4/L33-34); and at least one data channel within the substrate body in communication with at least one data port and at least one of the sockets (C4/L25-46 & Fig. 4); and
- at least one fluid input port (Fig. 3 (81)); at least one microscale fluid flow channel (see channels Fig. 3 (81-84)); and at least one operative device (C6/L35-40 & Fig. 3 (100, 60, 70)).

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-9, 12-13, 15-16, 21-23, 25-26, 30-33, 37, 46, 48, 51-53 & 60-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Bennett et al. (US 6,494,614).

Regarding Claim 1, Bennett et al. discloses a microfluidic substrate assembly comprising:

- a substrate body (Fig. 1 (40, 48, 54, 62, 68, 76)) comprising:
- at least one fluid inlet port (C5/L16 & Fig. 1 (42));
- at least one microscale fluid flow channel (C5/L18 & Fig. 1 (44)) within the substrate in fluid communication with the inlet port; and



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- a plurality of sockets (see around gaskets, Fig. 1 (20, 22, 24, 25, 27 28)), each socket configured to receive an operative component (e.g., pump 1 & 2, C4/L14 & Fig. 1 (30, 32)), wherein at least one socket is in communication with the microscale fluid flow channel (C4/L14-16).

Regarding Claims 2-9, 12, 13, 15, 16 & 21, Bennett et al. further discloses the microfluidic substrate assembly wherein:

- the substrate body is a multi-layer laminated substrate (Abstract & Figs. 1 & 2);
- a housing (e.g., top & bottom cover sheets, C5/L23-24 & Fig. 1 (34, 82)), the substrate body being positioned in the housing (see Fig. 2);
- the substrate assembly is generally planar (see Fig. 2);
- the plurality of sockets are located in an upper surface of the generally planar body (see Fig. 2);
- the plurality of sockets are located in a grid array (see Figs. 1 & 2);
- at least one of the sockets is in fluid communication with the microscale fluid flow channel (see Figs. 1-2 & C4/L14-29);
- at least one of the sockets is in fluid communication with at least one other of the sockets (see holes (36, 38) where the sockets sit in fluid communication, C4/L20-29);
- multiple sockets of the sockets have the same configuration (see Fig. 1);
- the substrate body further includes at least one fluid outlet port in fluid communication with the fluid inlet port (Claim 1);

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- a fluid reservoir in fluid communication with the microscale fluid flow channel (C3/L64-65);
- at least one data port (e.g., detector pads, C5/L60 & Fig. 1 (70)); and at least one data channel (e.g., detector channel, C5/L59 & Fig. 1 (76)) within the substrate body in communication with the data port;
- the data channel is in electrical communication with the data port (e.g., electrical signal, C5/L61); and
- the substrate body further comprises a data output port in communication with the data channel (e.g., detector pads, C5/L60 & Fig. 1 (70)).

Regarding Claim 22, Bennett et al. disclose a microfluidic substrate assembly comprising:

- a generally planar multi-layer laminated substrate (Abstract & Figs. 1 & 2) comprising:
  - at least one fluid inlet port (C5/L16 & Fig. 1 (42));
  - at least one microscale fluid flow channel (C5/L18 & Fig. 1 (44)) at each of multiple levels within the multi-layer substrate (see Fig. 1), in fluid communication with the inlet port for transport of fluid to be tested;
  - at least one microscale via extending between levels within the multi-layer laminated substrate for fluid communication between microscale fluid flow channels on different levels (see Fig. 1); and

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- a plurality of sockets (see around gaskets, Fig. 1 (20, 22, 24, 25, 27 28)), each socket configured to receive an operative component (e.g., pump 1 & 2, C4/L14 & Fig. 1 (30, 32)), wherein at least one socket is in communication with at least one microscale fluid flow channel (C4/L14-16).

Regarding Claims 23, 25, 26, 30, Bennett et al. further disclose the microfluidic substrate assembly wherein the multi-layer laminated substrate further comprises:

- at least one data port (e.g., detector pads, C5/L60 & Fig. 1 (70)); and at least one data channel (e.g., detector channel, C5/L59 & Fig. 1 (76)) at each of more than one level within the multi-layered laminated substrate in communication with the data port; and at least one data tap (Fig. 1 (66)) extending between levels within the multi-layered laminated substrate for communication between data channels on different levels;
- each of the sockets is in communication with at least one other of the sockets (see holes (36, 38) where the sockets sit in fluid communication, C4/L20-29);
- the microfluidic substrate assembly further comprises a pair of rigid plates (Fig. 1 (34, 82)), the laminated substrate being sandwiched between the rigid plates (see Figs. 1, 2); and
- at least first and second layers of the multi-layer laminated substrate are selectively welded to each other to form a fluid-tight seal at least along one microscale fluid flow channel within the multi-layer laminated substrate (e.g., thermal bonding, C6/L19-20).

Regarding Claim 31, Bennett et al. discloses a microfluidic substrate assembly comprising: a substrate body comprising:

- at least one fluid inlet port (C5/L16 & Fig. 1 (42));
- at least one microscale fluid flow channel (C5/L18 & Fig. 1 (44)) within the substrate body in fluid communication with at least one fluid inlet port for transport of fluid to be tested;
- a plurality of sockets (see around gaskets, Fig. 1 (20, 22, 24, 25, 27 28)), each configured for receiving an operative component (e.g., pump 1 & 2, C4/L14 & Fig. 1 (30, 32)) and in communication with at least another of the sockets, wherein at least one socket is in communication with the microscale fluid flow channel (C4/L14-16); and
- at least one operative component mounted in a corresponding one of the sockets (see Fig. 2).

Regarding Claims 32, 33, 37, 46, 48 & 51, Bennett et al. further disclose the microfluidic substrate assembly wherein:

- the substrate body comprises a multi-layer laminated substrate (Abstract & Figs. 1 & 2);
- the at least one of the sockets is in fluid communication with the microscale fluid flow channel (see Figs. 1-2 & C4/L14-29);

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- the substrate body further comprises at least one fluid outlet port in fluid communication with at least one fluid inlet port (Claim 1);
- the at least one operative component comprises a device operative: separation column or chamber (see separation channels in modules Fig. 1 (54, 62));
- the at least one operative component is operative to directly contact a fluid in the microscale fluid flow channel (see Fig. 2); and
- the operative component is permanently mounted in a socket (see Fig. 2).

Regarding limitations recited in Claim 52 which are directed to a manner of operating disclosed device (e.g. “using potting compound”), it is noted that neither the manner of operating a disclosed device nor material or article worked upon further limit an apparatus claim. Said limitations do not differentiate apparatus claims from prior art. See MPEP § 2114 and 2115. Further, it has been held that process limitations do not have patentable weight in an apparatus claim. See *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969) that states “Expressions relating the apparatus to contents thereof and to an intended operation are of no significance in determining patentability of the apparatus claim.”

Regarding Claims 53, 60 & 61, Bennett et al. further disclose the microfluidic substrate assembly wherein:

- the operative component is removably mounted in a socket (see Fig. 2, it is noted that any component can be removed/separated);

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- at least one data port (e.g., detector pads, C5/L60 & Fig. 1 (70)); and at least one data channel (e.g., detector channel, C5/L59 & Fig. 1 (76)) within the substrate body in communication with at least one data port; and
- a substrate body (Fig. 1 (40, 48, 54, 62, 68, 76)) defining: at least one fluid input port (C5/L16 & Fig. 1 (42)); at least one microscale fluid flow channel (C5/L18 & Fig. 1 (44)); and at least one operative device (e.g., pump 1 & 2, C4/L14 & Fig. 1 (30, 32)).

### ***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (US 5,580,523) and further in view of Benavides et al. (US 6,443,179).

Regarding Claim 14, Bard fails to disclose the substrate body is formed of PEEK.

Benavides et al. discloses a microfluidic device (Abstract & Fig. 23) with a substrate formed of PEEK (C8/L62-63 & Fig. 23 (12)).

Bard and Benavides et al. are analogous because these references are directed to microfluidic devices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make substrate with PEEK (C8/L62-63), as taught by Benavides et al., to the microfluidic synthesizer, as taught by Bard, since PEEK is a well known in art as electrically insulating thermoplastic which is being used in pumps, compressors, wiring insulation and ultra-high vacuum applications.

10. Claims 22-25, 30, 32 & 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (US 5,580,523) and further in view of Bennett et al. (US 6,494,614).

Regarding Claim 22, Bard discloses a microfluidic substrate assembly comprising:

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- a generally planar substrate (see Fig. 3) comprising:
- at least one fluid inlet port (Fig. 3 (81));
- a plurality of sockets (see Figs. 1d & 3), each socket configured to receive an operative component (C6/L35-40 & Fig. 3 (100, 60, 70)), wherein at least one socket is in communication with at least one microscale fluid flow channel (see Fig. 3).

However, Bard fails to disclose a multi-layer substrate.

Bennett et al. discloses a microfluidic substrate assembly comprising:

- a generally planar multi-layer laminated substrate (Abstract & Figs. 1 & 2) comprising:
- at least one fluid inlet port (C5/L16 & Fig. 1 (42));
- at least one microscale fluid flow channel (C5/L18 & Fig. 1 (44)) at each of multiple levels within the multi-layer substrate (see Fig. 1), in fluid communication with the inlet port for transport of fluid to be tested;
- at least one microscale via extending between levels within the multi-layer laminated substrate for fluid communication between microscale fluid flow channels on different levels (see Fig. 1); and
- a plurality of sockets (see around gaskets, Fig. 1 (20, 22, 24, 25, 27 28)), each socket configured to receive an operative component (e.g., pump 1 & 2, C4/L14



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& Fig. 1 (30, 32)), wherein at least one socket is in communication with at least one microscale fluid flow channel (C4/L14-16).

Bard and Bennett et al. are analogous because these references are directed to microfluidic devices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use multi-layer substrate with five unit process operation modules (C4/L56-59), as taught by Bennett et al., to the microfluidic synthesizer, as taught by Bard, to allow different levels of processing modules within the substrate.

Regarding Claims 23-25 & 30, modified Bard further discloses the microfluidic substrate assembly wherein the multi-layer laminated substrate further comprises:

- at least one data port (C4/L33-34); and at least one data channel at each of more than one level within the multi-layered laminated substrate in communication with the data port and at least one of the sockets (C4/L25-46 & Fig. 4); and at least one data tap extending between levels within the multi-layered laminated substrate for communication between data channels on different levels (C4/L25-46);
- at least one layer of the multi-layered laminated substrate is formed of plastic (C5/L17) and the substrate assembly is operative and fluid tight (e.g., extreme conditions, supercritical temperatures and pressures, C3/L54-55);

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- each of the sockets is in communication with at least one other of the sockets (see Fig. 3);
- at least first and second layers of the multi-layer laminated substrate are selectively welded to each other to form a fluid-tight seal at least along one microscale fluid flow channel within the multi-layer laminated substrate (e.g., extreme conditions, supercritical temperatures and pressures, C3/L54-55).

Regarding Claim 24, modified Bard fails to disclose fluid tight at a fluid pressure in excess of 100 psig. It would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the multi-layered substrate to withstand environment which it is being used in to prevent leakage.

Regarding Claim 32, Bard fails to disclose a multi-layer substrate.

Bennett et al. discloses the microfluidic substrate assembly wherein the substrate body comprises a multi-layer laminated substrate (Abstract & Figs. 1 & 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use multi-layer substrate with five unit process operation modules (C4/L56-59), as taught by Bennett et al., to the microfluidic synthesizer, as taught by Bard, to allow different levels of processing modules within the substrate.

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Regarding Claim 59, Bard fails to disclose use of a plug. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plug to prevent leakage when the socket is not in use with an operative component.

11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (US 5,580,523) in view of Bennett et al. (US 6,494,614) and further in view of Benavides et al. (US 6,443,179).

Regarding Claim 27, modified Bard fails to disclose the substrate body is formed of PEEK.

Benavides et al. discloses a microfluidic device (Abstract & Fig. 23) with a substrate formed of PEEK (C8/L62-63 & Fig. 23 (12)).

Modified Bard and Benavides et al. are analogous because these references are directed to microfluidic devices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to make substrate with PEEK (C8/L62-63), as taught by Benavides et al., to the microfluidic synthesizer, as taught by Bard, since PEEK is a well known in art as electrically insulating thermoplastic which is being used in pumps, compressors, wiring insulation and ultra-high vacuum applications.

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12. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bard (US 5,580,523) in view of Bennett et al. (US 6,494,614) & Benavides et al. (US 6,443,179) and further in view of Vargo et al. (US 6,790,526).

Regarding Claims 28-29, modified Bard fails to disclose IR welding of the PEEK layer.

Vargo et al. disclose a use of infrared welding of thin films with use of IR absorbing additives (C56/Example XI).

Modified Bard and Vargo et al. are analogous because these references are directed to adhesion of thin films.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use IR welding, as taught by Vargo et al., to the microfluidic synthesizer with PEEK, as taught by modified Bard, to allow different levels of processing modules within the substrate.

13. Claims 14 & 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al. (US 6,494,614) and further in view of Benavides et al. (US 6,443,179).

Regarding Claim 14, Bennett et al. fails to disclose the substrate body is formed of PEEK.

Benavides et al. discloses a microfluidic device (Abstract & Fig. 23) with a substrate formed of PEEK (C8/L62-63 & Fig. 23 (12)).

Bennett et al. and Benavides et al. are analogous because these references are directed to microfluidic devices.

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It would have been obvious to one of ordinary skill in the art at the time of the invention to make substrate with PEEK (C8/L62-63), as taught by Benavides et al., to the microfluidic device, as taught by Bennett et al., since PEEK is a well known in art as electrically insulating thermoplastic which is being used in pumps, compressors, wiring insulation and ultra-high vacuum applications.

Regarding Claim 27, Bennett et al. fails to disclose the substrate is formed of PEEK.

Benavides et al. discloses a microfluidic device (Abstract & Fig. 23) with a substrate formed of PEEK (C8/L62-63 & Fig. 23 (12)).

It would have been obvious to one of ordinary skill in the art at the time of the invention to make substrate with PEEK (C8/L62-63), as taught by Benavides et al., to the microfluidic device, as taught by Bennett et al., since PEEK is a well known in art as electrically insulating thermoplastic which is being used in pumps, compressors, wiring insulation and ultra-high vacuum applications.

14. Claims 24 & 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al. (US 6,494,614).

Regarding Claim 24, Bennett et al. further disclose the microfluidic substrate assembly wherein at least one layer of the multi-layered laminated substrate is formed of plastic (C6/L5-20) and the substrate assembly is operative and fluid tight (e.g., bonding, C6/L16-20 & C7/L32-36).

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Bennett et al. discloses all of the claim limitations as set forth above. However, Bennett et al. fails to disclose fluid tight at a fluid pressure in excess of 100 psig. As the operation pressure are variables that can be modified, among others, by adjusting said microfluidic substrate, the pressure would have been considered a result effective variable by one having ordinary skill in the art at the time the invention was made. As such, without showing unexpected results, the claimed pressure cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine experimentation, the structure of the multi-layered substrate in the apparatus of Bennett et al. to obtain the desired balance between the construction cost and the operation pressure (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding Claim 59, Bennett et al. fails to disclose use of a plug. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a plug to prevent leakage when the socket is not in use with an operative component.

15. Claims 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bennett et al. (US 6,494,614) in view of Benavides et al. (US 6,443,179) and further in view of Vargo et al. (US 6,790,526).

Regarding Claims 28-29, modified Bennett et al. fails to disclose IR welding of the PEEK layer.

Vargo et al. disclose a use of infrared welding of thin films with use of IR absorbing additives (C56/Example XI).

Modified Bennett et al. and Vargo et al. are analogous because these references are directed to adhesion of thin films.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use IR welding, as taught by Vargo et al., to the microfluidic device with PEEK, as taught by modified Bennett et al., to allow different levels of processing modules within the substrate.

### ***Conclusion***

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Barth et al. (US 6,386,219) discloses a microfluidic device with manifolds (316, 318) attached;
- Tanga (US 6,525,343) discloses a microchip with reaction pool portions (11, 12);
- Parce et al. (US 6,306,659) discloses a microfluidic system; and
- Hahn et al. (PG Pub 2003/0012697) discloses a microfluidic device with a plurality of attachments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEAN KWAK whose telephone number is (571)270-7072. The examiner can normally be reached on M-TH, 5 am - 3:30 pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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29Apr09

/D. K./

Examiner, Art Unit 1797

/Lyle A Alexander/

Primary Examiner, Art Unit 1797